REMARKS

The application is believed to be in condition for allowance.

Status of the Claims

Claims 8-15 remain pending in this application.

Claim Rejections-35 USC §112

Claims 14 and 15 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed.

The specification states that glutamine peptide supports the octyl butyrate by acting as an energy supplement for cells, i.e., the "fuel". However, glutamine peptide is not considered equal to panthenol with respect to the activity of the energy supplement.

Indeed, as stated on page 7, second paragraph of the Declaration of October 26, 2009, panthenol guarantees the energy, and certainly not the synergistic contribution to the activity octyl butyrate as the glutamine peptide is described in the specification. The Declaration further states that panthenol is necessary to produce coenzyme A, and is a fundamental molecule for energetic metabolism in all cells of an organism, especially skin cells. That is, panthenol is a critical element in protein,

carbohydrate, lid metabolism and synthesis. Panthenol by a mechanism of "complexing" can act on the reactivation of cutaneous trophesim and on reepithelization. Thus, panthenol has a different function than glutamine peptide in that it enhances or guarantees the effect of glutamine peptide.

For these reasons, panthenol is listed separately with the liquid carrier, and not as an active ingredient that directly inhibits and/or delays hair loss.

Therefore, the claims are believed to be definite, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claims 8-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over DESJONQUERES US 6,001,378 (DESJONQUERES) in view of GREFF FR 2,740,331 (GREFF) and HINO et al. US 2003/0003072(HINO). This rejection is respectfully traversed.

DESJONQUERES discloses a composition for treating alopecia comprising an active principle containing: (i) peroxidized lipids and (ii) biologically active organosilicone derivatives. Methylsilanol aspartate hydroxyprolinate is one of the seven organosilicon derivatives disclosed. The Official Action recognized that DESJONQUERES fails to teach octyl butyrate, glutamine peptides, benzyl nicotinate and panthenol.

GREFF was offered for teaching using octyl butyrate and a cereal protein hydrolysate rich in glutamine for treating hair loss.

HINO was offered for teaching a composition of promoting hair growth with minoxidil or benzyl nicotinate, as well as optional compounds, such as panthenol.

The position of the Official Action was that it would have been obvious to combine the compositions taught by these three documents to form a single composition to be used for the same purpose.

However, the proposed combination fails to render obvious the claimed invention for the following three reasons:

I. The combination does not teach the composition of claims 11-15.

A) Independent claim 11

Claim 11 recites hydroxyproline and aspartic acid.

The present specification recognizes that the non-complexed hydroxyproline and aspartic acid are effective, e.g., on page 4, lines 24-29, whereas DESJONQUERES only discloses organosilicon derivatives.

Thus, there is no finding of fact as to hydroxyproline and aspartic acid, without the silanol complex, as recited in independent claim 11, having any effect on decreasing hair loss.

B) Independent claim 14

Claim 14 is directed to a composition with active ingredients that <u>consists of</u> octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate.

Accordingly, the proposed "three topically applied compositions taught by DEJONQUERES, GREFF and HINO to form a single composition" results in a composition of active ingredients other than those claimed to achieve a desired efficacy. In particular, DESJONQUERES requires peroxidized lipids and organosilicon derivatives to achieve a synergistic effect (See, e.g., the Abstract and column 4, lines 43-53.)

Thus, the combination fails to teach the composition with $\underline{\text{active}}$ ingredients consisting of those defined by claims 14 and 15.

II. There would have been no reason to approach claim 14.

Claim 14 is directed to a composition with active ingredients that <u>consist of</u> octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate.

Again, DESJONQUERES <u>requires</u> peroxidized lipids and organosilicon derivatives to achieve <u>a synergistic</u> <u>effect</u> (See, e.g., the Abstract and column 4, lines 43-53.)

Thus, one of ordinary skill in the art would have been strongly discouraged from approaching the composition of claim 14 (and dependent 15), which consist of a defined group of active ingredients, as it would have required the removal of a necessary component from DESJONQUERES. This modification would have rendered the composition of DESJONQUERES unsatisfactory for its intended use.

As pointed out in MPEP 2143.01 V:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Thus, one of ordinary skill in the art would have been strongly discouraged from discarding an active ingredient from DESJONQUERES which is required to achieve the desired synergistic effect.

III. The combination fails to recognize the superior results.

As noted in MPEP 716.02(b):

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In the instant case, GREFF would be considered the closest prior art, as GREFF suggests two of the four active ingredients claimed, i.e., octyl butyrate and a cereal protein hydrolysate rich in glutamine. This is similar to "Composition A" previously presented in the first declaration signed and dated October 14, 2009.

In this first declaration, the results illustrate that the efficacy of the composition of independent claims 8 and 14 ("Composition B"), which includes active ingredients octyl butyrate glutamine peptides, monomethylsilanol-hydroxyproline aspartate and benzyl nicotinate, along with panthenol, is superior to a composition of octyl butyrate and glutamine alone (Composition A).

For example, Composition B, or the claimed invention, was superior to Composition A, or that suggested by GREFF, in that Composition B reduced hair loss in one third the time and using half as many applications as that of Composition A. See, e.g., the table on p. 7. That is, the claimed invention is faster in its efficacy than a composition of octyl butyrate and glutamine alone.

Although the Official Action required further time comparisons, the <u>speed</u> of efficacy is adequately compared in the declaration in order to conclude that the claimed invention is superior.

Moreover, as both DESJONQUERES and HINO offer a laundry list of possible active ingredients and other ingredients, this fact further supports the conclusion that the superior results are unexpected.

Again, as explained previously, the second declaration signed and dated October 23, 2009 explains the properties of the individual components, as well as the aim of the claimed invention, i.e., to interfere with various mechanisms of hair loss without exerting any local pharmacological or systemic action.

With respect to independent claim 11, as evidenced by the discussion in the specification (e.g., page 4, lines 20-29 and page 5, lines 8-19 and 25-35) and the declaration signed and dated October 23, 2009, the combination of hydroxyproline and aspartic acid contribute to the anti-hair loss activity, which the proposed combination fails to suggest.

That is, DESJONQUERES requires peroxidized lipids and organosilicon derivatives in order to achieve a <u>synergistic</u> <u>effect</u> (See, e.g., the Abstract and column 4, lines 43-53.) Monomethylsilanol-hydroxyproline aspartate (as recited in independent claims 8 and 11) is neither claimed nor exemplified as a preferred component. Thus, in view of DESJONQUERES, the superior results achieved by the claimed invention are further unexpected.

Thus, the proposed combination fails to suggest the superior results obtained by combining the composition of GREFF with specific ingredients suggested by DESJONQUERES and HINO, e.g., as recited in claims 8-10 and 14-15, or with the combination of hydroxyproline and aspartic acid themselves (which is not suggested by any cited document) and with specific ingredients suggested by HINO, e.g., as recited in independent claims 11-13

IV. Conclusion

Therefore, as the proposed combination (1) fails to teach or suggest the features of the claimed invention of 11-15, (2) teaches away from claims 14-15, and (3) fails to suggest the unexpected superior results of the claims 8-15, withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Docket No. 5002-1074 Appln No. 10/537,296

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,
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